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EXAMINER	
KOROMA, BARBA M	
ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 09/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/051,307	DAI ET AL.	
	Examiner	Art Unit	
	Barba M. Koroma	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5,7,9,11,12 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,2,5,7,9,11 and 12* is/are rejected.

7)☒ Claim(s) *16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/12/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-2, 5, 7, 9, 11-12, and 16 in the paper filed July 30, 2004, is hereby acknowledged. Appropriate cancellation of non-elected claims is also acknowledged.

Specification

2. Specification is objected to and correction is requested for the following:

Lines 4 and 8 of paragraph 2, page 13, read 'lof ' and 'IIIof ' instead of 'I of' and 'IIII of' respectively.

Sequence identification numbers (SEQ ID Nos.) are not used in referring to specific nucleotide sequences. Examples are found on page 24, lines 5, 6, 9, 11-12, 15, 16, 18 and 19.

The last paragraph of page 12 discusses Figure 1 and recites 'shaded area 100', 'underlined area 102', and 'underlined area 104'. It is not clear what is being referred to since these numbers are missing in the brief description of the figure section on page 4, as well as in the list of figures.

The specification contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. The hyperlinks on page 13, lines 1-2, and page 14, lines 22-23, must be changed to normal text, listing only the Internet address. See MPEP § 608.01.

On page 24, lines 29-32, the specifications refer to bands 301-304 and lane 300 of figure 7. However, the figure has labels 400-404, not 300-304. Similarly, the specification refers to lanes 400-404 of figure 6 on page 25, lines 14-16. However, the figure has lanes 400-404. Clarification and or correction is required.

The lanes of figures 10 and 11 are not labeled as indicated on pages 28, lines 2-6 and page 29, lines 9-13, respectively.

Applicant should modify the specification appropriately.

Claim Objections

3. Claim 5 and 16 are objected to for the following reasons:

The article “the” preceding the word "claim" in claim 5 should be deleted.

Claim 16 recites, "SEQ ID NO. 1 coding for the *pin1* promoter". SEQ ID No.1 does not code for the pin1 promoter, it is the promoter. DNA sequences do not encode promoters. Correction is requested.

Claim Rejections – 35 USC 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 5, 7, 9 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 11, the statement "isolated polynucleotide having at least 70% sequence identity with SEQ ID NO. 1 and proteinase inhibitor 1 (*pin1*) gene promoter activity" renders the claim indefinite. It is unclear how a polynucleotide can have percent identity with a promoter activity as implied by the recitation. It is suggested that the term --having-- be inserted into line 3 of claim 1 and line 5 of claim 11 before "*pin1*".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 2, 5, 7, 9, 11, and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to an isolated polynucleotide having at least 70% sequence identity with SEQ ID No. 1, or wherein the polynucleotide molecule is selected from the group consisting of SEQ ID No1, SEQ ID No 2, SEQ ID No 3, or any functional fragments thereof having or encoding *pin1* gene promoter activity, an expression vector comprising the polynucleotide, a plant cell, and transgenic plant comprising the polynucleotide, method for producing a gene product in a transformed plant cell, a chimeric gene comprising a polynucleotide having at least 70% sequence identity with SEQ ID No. 1, and *pin1* gene promoter activity operably linked to a structural gene; method of transforming a plant, and expressing a chimeric gene in the transformed plant cell to produce the gene product.

The specification indicates that the promoter elements of the pin1 gene were isolated from potato genomic DNA using the genome Walker kit from CLONETECH. The DNA sequences of the promoters of three isoforms of the

pin1 gene are shown in Figures 1-3 (SEQ ID NOs: 1-3, respectively; page 23, line 24 to page 24, line 23). Northern analyses showed that the pin1 promoter is induced by dark treatment and ethylene treatment (page 25, lines 13-19 and page 27, line 30 to page 28, line 7). The specification further indicates that a *pin1* promoter-gus fusion reporter gene was inserted into an expression vector and stably transformed into a tobacco cell culture and potato plants. GUS expression was observed in 100 independently transformed calli and 30 independently transformed plants (page 26, line 11 to page 27, line 9).

The specification does not describe any isolated polynucleotide having at least 70% sequence identity with SEQ ID No. 1 that retain pin1 gene promoter activity, other than SEQ ID Nos: 1-3. The specification does not describe all of the sequences of SEQ ID No. 1 that are essential to its promoter activity, or those sequences of SEQ ID No. 1 that can be changed without affecting its activity. SEQ ID No. 1 consists of 1595 nucleotide sequences. A sequence that shares as little as 70% identity with SEQ ID No. 1 will differ in 479 nucleotides. The specification does not provide any information concerning which 479 nucleotides of SEQ ID No. 1 may be changed, and to what they may be changed. The specification does not correlate pin1 gene promoter activity with any structures other than the nucleotide sequences of SEQ ID Nos: 1-3.

The specification also does not describe any fragments of SEQ ID Nos: 1-3 that retain pin1 gene promoter activity. As discussed above, the specification does

not describe all of the sequences of SEQ ID No. 1, or SEQ ID Nos: 2, and 3, that are essential to their promoter activities. The specification defines "core promoter" as a promoter that contains essential nucleotide sequences for promoter function, including the TATA box and transcription start site, and indicates that a core promoter may not have detectable activity in the absence of specific sequences that may enhance the activity (page 5, lines 28-31). The specification does not describe all of the sequences that make up the core of the promoters of SEQ ID Nos 1-3 that are minimally required for activity. Given the breadth of the claims encompassing isolated polynucleotides having at least 70% identity to SEQ ID No: 1, and fragments of SEQ ID Nos: 1-3, and the lack of written description as discussed above, the specification fails to provide an adequate written description of the multitude of polynucleotides encompassed by the claims.

6. Claims 1, 2, 5, 7, 9, 11, and 12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the promoter sequence of SEQ ID Nos. 1, 2 and 3, does not reasonably provide enablement for isolated polynucleotides having at least 70% sequence identity to SEQ IDF No. 1 or fragments of SEQ ID Nos. 1-3, that retain *pin1* promoter activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with these claims.

The claims are broadly drawn to an isolated polynucleotide having at least 70% sequence identity with SEQ ID No. 1, or wherein the polynucleotide molecule is selected from the group consisting of SEQ ID No1, SEQ ID No 2, SEQ ID No 3, or any functional fragments thereof having or encoding *pin1* gene promoter activity, an expression vector comprising the polynucleotide, a plant cell, and transgenic plant comprising the polynucleotide, method for producing a gene product in a transformed plant cell, a chimeric gene comprising a polynucleotide having at least 70% sequence identity with SEQ ID No. 1, and *pin1* gene promoter activity operably linked to a structural gene; method of transforming a plant, and expressing a chimeric gene in the transformed plant cell to produce the gene product.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The specification indicates that the promoter elements of the pin1 gene were isolated from potato genomic DNA. The corresponding isoforms I, II, and III are shown as SEQ ID Nos. 1-3, and Figures 1-3 respectively (page 23, line 24 to page 24, line 23). Northern blot analyses showed that the pin1 promoter is induced by dark treatment and ethylene treatment (page 25, lines 13-19 and page 27, line 30 to page 28, line 7). A *pin1* promoter-gus fusion reporter gene inserted into an expression vector was used to stably transform cultured tobacco cells and potato plants. GUS expression was observed in 100 independently transformed calli and 30 independently transformed plants (page 26, line 11 to page 27, line 9).

The specifications do not teach any isolated polynucleotide having at least 70% sequence identity with SEQ ID No. 1 that retain pin1 gene promoter activity, other than SEQ ID Nos: 1-3. The specification does not teach all of the sequences of SEQ ID No. 1 that are essential to its promoter activity, or those sequences of SEQ ID No. 1 that can be changed without affecting its activity. SEQ ID No. 1 consists of 1595 nucleotide sequences. A sequence that shares as little as 70% identity with SEQ ID No. 1 will differ in 479 nucleotides. The specification does not provide any guidance concerning which 479 nucleotides of SEQ ID No. 1 may be changed, and what they may be changed to.

Furthermore, the specification does not teach any fragments of SEQ ID Nos. 1-3 that retain pin1 gene promoter activity. The specification does not teach all of the

sequences of SEQ ID No. 1, or SEQ ID Nos: 2, and 3, that are essential to their promoter activities. The specification defines "core promoter" as a promoter that contains essential nucleotide sequences for promoter function, including the TATA box and transcription start site, and indicates that a core promoter may not have detectable activity in the absence of specific sequences that may enhance the activity (page 5, lines 28-31). The specification does not teach all of the sequences that make up the core of the promoters of SEQ ID Nos. 1-3 that are minimally required for activity. The state-of-the-art is such that one of skill in the art cannot predict which nucleic acids that are 70% sequence identical to SEQ ID No.1-3 will retain the pin1 activity of SEQ ID No. 1 or what fragments of SEQ ID Nos. 1-3 will retain pin1 promoter activity. Even minor changes to a promoter can abolish promoter activity as taught by Kim et al (Plant Mol Biol 24:105-117; 1994, pp 105, abstract, lines 9-14, results section p107-113).

Given the breadth of the claims, the lack of guidance of the specification as discussed above and the unpredictability in the art, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

Conclusion

7. Claims 1, 2, 5, 7, 9, 11, 12, and 16 are deemed free of the prior art given the failure of the prior art to teach or fairly suggest SEQ ID Nos. 1, 2, and 3, or sequences at least 70% identical to SEQ ID No. 1.

Contact Information

8. Any inquiry concerning this or earlier communications from the Examiner should be directed to Barba Koroma, whose telephone number is 571-272-0899. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as

well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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